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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/084,691	05/26/1998	JENS BUKH	2026-4116US2	5825

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding..

Office Action Summary	Application No.	Applicant(s)	
	09/084,691	BUKH ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,5,11-16,19,32-44 and 46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-44 and 46 is/are rejected.
- 7) ☒ Claim(s) 4,5,11-16 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Currently, claims 4, 5, 11-16, 19, 32-44, and 46 are pending in the application.
2. In the prior action, mailed on May 18, 2004, claims 1 and 3-59 were pending in the application, with claims 4, 5, 11-16, 19, 32-44, 46, and 59 rejected; and claims 1, 3, 6-10, 17, 18, 20-31, 45, and 47-58 withdrawn as to non-elected inventions. In the Response, filed on October 18, 2004, claims 4, 5, 15, 16, 19, 32, 37, 38, and 46 were amended; and claims 1, 3, 6-10, 17, 18, 20-31, 45, and 47-59 were cancelled.
3. Currently, claims 4, 5, 11-16, 19, 32-44, and 46 are pending and under consideration.
4. Because this action raises new grounds of rejection, it is being made Non-Final.

Sequence Listing

5. **(Prior Objection- Withdrawn)** The specification is objected to for referring to sequences without also identifying them by the sequence identifier assigned to them in the sequence listing as required by 37 CFR 1.821(d). The Applicant traverses this objection on the grounds that the sequence identifiers for the indicated sequences were presented in the Figures disclosing them, and that the sequence identifiers need not be inserted into the application text where such is the case. This argument is found persuasive. The objection is therefore withdrawn.

Claim Objections

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6. **(Prior Rejection- Withdrawn)** Claims 32-44, 46, and 59 were objected to because of the following informalities: the claims refer to sequences in the application without identifying them by SEQ ID NO. The Applicant traverses the objection of claims 32 and 38 on the basis that the figures are referred to for the full scope of information disclosed therein, and that the information therein is not easily described without reference to the figure. This argument is found persuasive. The objection is therefore withdrawn.

7. **(New Objection-Necessitated by Amendment)** Claims 4 and 5 are objected to because of the following informalities: these claims have been amended to read on a protein either "encoded by a gene sequence SEQ ID NO: 154," or "having an amino acid sequence of SEQ ID NO: 206." It is suggested that the claims be amended to read on a protein encoded by - - the - - gene sequence SEQ ID NO: 154, or having - -the- - amino acid sequence of SEQ ID NO: 206 to clarify that the claims read on the full length protein. Appropriate correction is required.

It is noted that, because claims 4 and 5 refer to a protein, whereas claims 32 and 38 refer to peptides, claims 4 and 5 are read as describing a full length protein of SEQ ID NO: 206.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. **(Prior Rejection- Withdrawn)** Claims 32-37, 43, and 59 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims have

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been amended to read on genotype-specific peptides having amino acids deduced from domains in the HCV core protein of SEQ ID NO: 206 as deduced from the information presented in Figure 7J. From the Applicant's arguments, the claims are read as reading on any peptide comprising at least 8 residues from SEQ ID NO: 206, wherein the 8 residues correspond to a region in the alignment of Figure 7J comprising a lower case letter (representing variation in that position among the HCV subtypes represented in that figure). It is noted that, because the claims read on a peptide having such a region, and because the term "having" is considered to be the equivalent of the term "comprising" (MPEP 2111.03), the claimed peptides are not considered limited to peptides having only such residues from SEQ ID NO: 206. So long as the peptides comprise at least 8 such residues from the indicated sequence, the peptide may also include other residues and still fall within the scope of the claims. On this basis, the rejection is withdrawn.

10. **(Prior Rejection- Withdrawn)** Claims 38-42, 44, 46, and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims have been amended to read on peptides comprising at least 8 residues in a universally conserved amino acid domain in the HCV core protein of SEQ ID NO: 206. From the Applicant's arguments, this language is read as requiring that the claimed peptides comprise at least 8 consecutive residues of SEQ ID NO: 206, wherein the 8 residues correspond to a region in the alignment in Figure 7J comprising only capital letters (representing conservation of the amino acids among the subtypes represented in the figure). It is noted that, because the claims read on a peptide having such a region, and because the term "having" is considered to be the equivalent of

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the term “comprising” (MPEP 2111.03), the claimed peptides are not considered limited to peptides having only such residues from SEQ ID NO: 206. So long as the peptides comprise at least 8 such residues from the indicated sequence, the peptide may also include other residues and still fall within the scope of the claims. On this basis, the rejection is withdrawn.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. **(Prior Rejection- Withdrawn)** Claims 19 and 46 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic HCV compositions, does not reasonably provide enablement for anti-HCV vaccines comprising either SEQ ID NO: 206 or a fragment thereof. The claims have been amended to read on immunogenic compositions rather than on vaccines. In view of this amendment, the rejection is withdrawn.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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14. **(Prior Rejection- Maintained in part)** Claims 32-44, 46, and 59 were rejected under 35 U.S.C. 102(b) as being anticipated by DeLeyes et al. (EP 0 489 968 A). Claim 59 has been cancelled from the application. The rejection is therefore withdrawn from this claim as moot. The remaining claims have been amended to require that the claimed genotype-specific or universally conserved peptides are peptides comprising an appropriate sequence from SEQ ID NO: 206. The Applicant's arguments that the DeLeyes reference does not teach or suggest any universally conserved peptides of at least 8 residues according to Fig 7J is found persuasive. The rejection is therefore withdrawn from claims 38-42 and 44. However, the reference does appear to disclose two peptides that would meet the requirements for the claimed genotype-specific peptides of claims 32-37, 44, and 46.

As was indicated above, the claims drawn to genotype-specific peptides are being read as including any peptide comprising a sequence of SEQ ID NO: 206 wherein the region of the proteins in Fig 7J corresponding to that peptide have at least one lower case letter in at least one of the HCV types (1-6) or the consensus sequence. The DeLeyes reference discloses two such peptides: those identified as Peptide IIa (corresponding to residues 8-18 of SEQ ID NO: 206) and Peptide IV (corresponding to residues 37-56 of SEQ ID NO: 206) on page 3 of the reference. In view of these teachings, the rejection is maintained over claims 32-37, 43, and 46 for the reasons above, and the reasons of record.

15. **(Prior Rejection- Withdrawn)** Claims 32, 37, 43, and 46; and claims 38, 44, and 46 were rejected under 35 U.S.C. 102(a) as being anticipated by Shirai et al., J Virol 68(5): 3334-3342. As noted above, these claims have been amended to limit the claimed peptides to those

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derived from SEQ ID NO: 206. The peptides of the Shirai reference vary from the sequences of SEQ ID NO: 206. The rejection is therefore withdrawn.

16. **(Prior Rejection- Restated and Maintained)** Claims 38-42, 44, 46, and 59 were rejected under 35 U.S.C. 102(b) as being anticipated by Ferroni et al., J Clin Microbiol 31(6): 1586-91. The claims have been amended as indicated above. As noted by the Applicant, the peptides disclosed by Ferroni do not read on universally conserved peptides as determined by the information in Figure 7J. However, as the peptides of Ferroni do correspond to peptides of SEQ ID NO: 206, the reference would appear to be teaching genotype-specific peptides from SEQ ID NO: 206. The rejection is therefore withdrawn from claims 38-42, 44, and (cancelled claim) 59, but is extended to claims 32-37 and 43, and maintained over claim 46.

17. **(Prior Rejection- Withdrawn)** Claims 32-37, 43, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Machida et al., Hepatology 16: 886-91 (of record in the May 1998 IDS). The claims have been amended to read on peptides comprising sequences of SEQ ID NO: 206. As asserted by the Applicant, the peptides of Machida do not correspond to SEQ ID NO: 206. The rejection is therefore withdrawn in view of the arguments and the amendments to the claims.

18. **(New Rejection)** Claims 32, 37, 38, 43, 44, and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Chien et al. (U.S. Patent 6,054,264). The claims have been amended to read on peptides including a sequence of SEQ ID NO: 206. As indicated above, the claims also require that the peptides must have at least 8 residues within a conserved, or genotype-specific

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region of SEQ ID NO: 206. However, because the claims read on peptides “having” such sequences, and not “consisting of” them, the peptides of a universally conserved peptide, for example, may also include residues from a genotype-specific region so long as at least 8 residues from a universally conserved region are present. See e.g., specification, page 59 (teaching universal peptides as including peptide domains 93-108, 122-138, and 165-181 which have non-conserved residues as well as conserved domains). The claims as presently drafted are therefore read as including any peptide comprising, respectively, a genotype-specific or a universally conserved domain, from SEQ ID NO: 206, but not limited to peptides including only such domains. Because the term “having” is considered open language, the claims permit the presence of residues other than, respectively, those of a genotype-specific or universally conserved domain of SEQ ID NO: 206 in the peptides.

Chien teaches the use of peptides to screen for antibodies against HCV antigens. Among the peptides disclosed by Chien is the peptide of SEQ ID NO: 30 (Table 10, columns 19 and 20). This peptide included both universally conserved, and genotype specific domains. Thus, the peptide falls within both categories of peptides. In view of these teachings, the reference anticipates both sets of claims (i.e. those to genotype-specific peptides, and those to universal peptides). At least with respect to the universal peptides, the rejection may be overcome by limiting the claimed peptides to those - - consisting of - 8 residues of a universally conserved domain of SEQ ID NO: 206.

19. **(New Rejection)** Claims 32, 37, 38, 43, 44, and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Miyamura et al. (U.S. 5,856,437). The claims have been described above.

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The reference teaches a polypeptide comprising sequences corresponding to both conserved and genotype-specific regions of SEQ ID NO: 206. See e.g. Figure 1. The reference therefore anticipates the indicated claims.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. **(Prior Rejection- Withdrawn)** Claims 4 and 5 were rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the teachings of Li et al., Biochem Biophys Res Comm 199(3): 1474-81 (of record in the IDS of May 26, 1998); or of Takeuchi et al., J Gen Virol 71: 3027-33 (of record in the May 1998 IDS). The claims have been amended to read on SEQ ID NO: 206. In view of this amendment of the claims, the rejection is withdrawn.

22. **(Prior Rejection- Withdrawn)** Claims 4, 5, 11-15, 16, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Takeuchi or Li as applied to claims 3 and 4 above, and further in view of Liao et al., U.S. Patent 5,645,983. The claims have been amended such that they are limited to compositions or methods involving SEQ ID NO: 206, or peptides thereof. In view of this amendment, the rejection is withdrawn.

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23. **(Prior Rejection- Withdrawn)** Claims 32-37, 43, and 46 were rejected under 35 U.S.C. 103(a) as being unpatentable over Li as applied to claims 3 and 4 above, and further in view of Chien et al., U.S. Patent 6,054,264. In view of the amendments to the claims, the arguments made pursuant thereto, and the New Rejection over Chien above, this rejection is withdrawn.

24. **(New Rejection)** Claims 33-36 and 39-42 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chien as applied to claims 32, 37, 38, 43, 44, and 46 above, and as applied in combination with Li in the prior action. As indicated above, the reference teaches the use of the peptide disclosed as SEQ ID NO: 30 for use in detecting anti-HCV antibodies. It would have been obvious to those in the art to use the peptide to detect any antibodies which would bind thereto, whether they target HCV generally, or specific subtypes thereof. Thus, the reference renders the indicated claims obvious.

25. **(New Rejection)** Claims 33-36 and 39-42 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyamura as applied to claims 32, 37, 38, 43, 44, and 46 above. As indicated above, the reference teaches a peptide comprising conserved and genotype specific regions of SEQ ID NO: 206. The reference teaches that the polypeptide may be used in methods for the detection of anti-HCV antibodies. Columns 2-3. From these teachings, it would have been obvious to those in the art to use the peptide to detect any antibodies which would bind thereto, whether they target HCV generally, or specific subtypes thereof. Thus, the reference renders the indicated claims obvious.

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Conclusion

26. Although not in allowable condition (see objection to claims 4 and 5 above, the subject matter of claims 4, 5, 11-16, and 19 appear to be allowable over the prior art. Claims 11-16, and 19 are objected to for depending from claims that are not in condition for allowance.

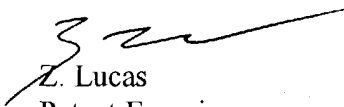
27. The following prior art reference is made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.


WO 95/12677. This reference teaches the sequence of SEQ ID NO: 206 (see e.g. Figure 4, lines corresponding to HCV subtype HK2 type 6a. However, this reference does not pre-date the priority date of the current application.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


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